IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327 MDL No. 2327**
THIS DOCUMENT RELATES TO ALL PLAINTIFFS LISTED IN EXHIBIT "A" TO THE INITIAL MOTION	**JOSEPH R. GOODWIN U.S. DISTRICT JUDGE**

PLAINTIFFS' REPLY IN FURTHER SUPPORT OF THEIR MOTION TO EXCLUDE CERTAIN OPINIONS AND TESTIMONY OF CHRISTINA PRAMUDJI, MD

PRELIMINARY STATEMENT

Defendants' opposition to the *Daubert* motion to preclude Dr. Pramudji from offering opinions regarding adequacy of warnings suggests that Dr. Pramudji should be permitted to offer these opinions based solely on her qualifications as a urogynecologist. But Plaintiffs' motion is not based on lack of qualifications, but rather lack of reliability. The deficiency in Dr. Pramudji's warnings opinions is that she did not consider or consult **any** standard whatsoever, leaving her opinion devoid of any verifiable methodology.

Similarly, the Defendants attempt to preserve Dr. Pramudji's opinions regarding the design of the subject devices, despite her lack of qualifications, as well as the absence of reliance on any objective, articulable standard in that area. Defendants instead substitute a literature review and her personal use of the product, in an attempt to make up for the lack of her qualifications and reliable methodology in this area. Finally, Defendants mischaracterize Plaintiffs' motion with regard to Dr. Pramudji's degradation opinions. Plaintiffs seek the same ruling as was issued in *Huskey*: that Dr. Pramudji is permitted to offer opinions regarding what

she has seen in clinical practice with regard to degradation, but she is not qualified to offer opinions on chemical degradation of polypropylene beyond what she has observed in her practice.

LEGAL ARGUMENT

A. Dr. Pramudji failed to apply any objective, reliable standard in offering her warning opinions, in violation of *Daubert*.

Plaintiff does not take issue on this motion with Dr. Pramudji's credentials. Rather, plaintiff's claim is that Dr. Pramudji's opinions are entirely subjective, without reference to any standard. The opposition brief fails to identify any standard or methodology applied by Dr. Pramudji, or any standard by which Dr. Pramudji's opinions on the warnings can be objectively evaluated. That gap is fatal to Dr. Pramudji's warning opinions. In *Sanchez v. Boston Scientific Corp.*, 2014 WL 4851989 (S.D.W. Va. Sept. 29, 2014), this Court precluded an expert's warning opinions because the expert applied no standard at all to support his opinions, concluding: "Dr. Slack's subjective and conclusory approach is evidence that his opinion is based on mere speculation and personal belief." *Id.* at *32. The same applies to Dr. Pramudji, who did not even know the purpose of the IFU. (Dr. Pramudji 9/17/14 Dep. Tr. at 78:15-21, attached as Exhibit A). Fatal to her opinion, Dr. Pramudji admitted that she did not know or "rely on any internal standards or any deposition testimony by any Ethicon witness as to what information needed to be in the IFU." (*Id.* at 17:6-19).

The Defendants' fallback position is that Dr. Pramudji should be permitted to testify that the risks of the mesh products were obvious to surgeons, and therefore the jury can find that there was no duty to warn at all. This transparent effort to justify the expert's deficient methodology is of no avail. Dr. Pramudji has performed no reliable or verifiable study or analysis of what surgeons may or may not know, in order to support a valid opinion that a

warning was not necessary on any particular issue. We simply have Dr. Pramudji's say so, which is insufficient under *Daubert*. *See Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 157 (1999) (stating that "nothing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert").

The Defendants and their experts apparently realize that the warnings are utterly deficient when evaluated under the proper standards. So, they take the unverifiable position that pelvic surgeons know of certain risks, thereby obviating the need to warn. (Defense Brief at 5-7). However, Dr. Pramudji admitted she lacked any foundation to opine as to what surgeons generally knew about the risks of pelvic surgery with mesh:

> Q. So simply saying that doctors would understand something or know something, you -- leaves questions as to what different doctors know. Let me rephrase it. You don't know the level of experience and knowledge of each doctor that considered using the Prolift. You haven't studied that question, right?
>
> A. No. That would be impossible to know.
>
> Q. And in providing warnings and information, you wouldn't want to assume that all physicians would have the same level of knowledge and experience as you would have, right?
>
> A. Well, I think the IFU clearly states that it's designed for pelvic surgeons that are familiar with the pelvic -- with pelvic surgery. So I think we're starting with a baseline knowledge.
>
> Q. Okay. Familiar with pelvic surgery with mesh. How many surgeries does that mean? Is there a defined number?
>
> A. No, there's not a defined number.
>
> Q. A doctor could do one procedure with mesh and think that he or she is familiar with that type of surgery, correct?
>
> A. I suppose a doctor could assume that. Yeah, some -- some doctors –

> Q. So saying that doctors need to be familiar with surgery with mesh really doesn't tell you anything about the level of knowledge and experience the doctor needs to have, correct?
>
> A. I mean, you're -- it's common sense basically that if there's a -- if you go through training and you have been trained on pelvic surgery in residency or after fellowship, then -- then you have a knowledge of pelvic surgery. I mean, it's obvious common sense that if you just do one that you're not familiar with it whether a doctor thinks that or not.
>
> Q. Telling doctors that they need to be familiar with pelvic surgery does not tell the doctor specifically what their level of knowledge and experience needs to be. It's not defined, correct?
>
> A. Yes. It's not defined. It's not specific. You're correct.

(Dr. Pramudji 9/17/14 Dep. Tr. at 82:22-84:12, Exhibit A). That testimony makes it clear that the defense expert cannot testify that risks were known to doctors without being warned. In fact, her statement that this is a matter of "common sense" takes the issue completely out of the realm of expert testimony.

In addition, this opinion is directly contradicted by the deposition testimony of various Ethicon employees. For example, Charlotte Owens testified that the IFU needed to "clearly and unambiguously communicate" necessary warnings, and they **"need[] to list each of the adverse reactions that were known to you in Medical Affairs."** (Charlotte Owens Dep. Tr. at 262:7-13, 309:23-310:3, attached as Exhibit B) (emphasis added). Similarly, David Robinson of Medical Affairs testified that the IFU **"should accurately represent what we knew to be risks,"** and that a complication would need to be listed if it had **"a frequency or a severity that had some implication for a risk/benefit ratio."** (David Robinson Dep. Tr. at 488:11-18, 489:4-10, 492:23-493:8, attached as Exhibit C) (emphasis added). Finally, Dr. James Hart, Chief Medical Officer of the Johnson & Johnson Global Surgery Group, testified that the purpose of the IFU is to:

> **provide a COMPLETE STATEMENT of what the company knows with regard to the indications, the contraindications, the warnings, the precautions and the adverse reactions for the device.**

(Dr. James Hart 12/20/13 Dep. Tr. at 800:3-8, attached as Exhibit D) (emphasis added).

The deposition testimony of Sean O'Bryan of regulatory affairs confirmed that Ethicon could not withhold warnings based on an assumption that surgeons would otherwise know the risks:

> Q: When you worked on that project, it was your understanding from an FDA regulatory perspective it would not be legitimate to not include warnings of potentially significant adverse events based on a decision that the surgeons would figure that out on their own?
>
> A: No, that's correct.

(Sean O'Bryan 5/18/12 Dep. Tr. at 107:14-21, attached as Exhibit E). This testimony invalidates the subjective, unsupported position by Dr. Pramudji that would allow Ethicon to fail to warn based on an unverifiable claim or assumption that physicians would know the risks without being warned. Of course, that is not a standard; rather, it is an unverifiable excuse created to explain the failure to provide warnings in accordance with the applicable standards.

B. Dr. Pramudji is not qualified to give opinions on the design of the mesh products, has relied on no objective standard in reaching her conclusions, and her opinions should be excluded.

Dr. Pramudji is admittedly not an expert in design, and her only design opinion is based on the feel of the device in her hands, and on patient results. (Plaintiffs' Brief at 9-10). Dr. Pramudji's use of mesh products does not, by itself, qualify her to opine regarding their design any more than a person is qualified to opine about a chair based on how it feels when she sits in it, and based on what she has observed when others sit in it. Defendants claim that the foundation of Dr. Pramudji's design opinions is her "extensive review of the medical literature as set forth throughout her reports." (Defense Brief at 13). A review of the literature does not

provide sufficient basis for Dr. Pramudji to offer a reliable design opinion unless she can identify an appropriate standard that she applied. *See Winebarger v. Boston Scientific Corp.*, No. 2:13-CV-28892, 2015 WL 1887222, at *14 (S.D. W. Va. Apr. 24, 2015) (finding that Dr. Schull had not reliably applied the principles learned through his experience and the literature to the facts of this case because he had not seen any standard operating procedures or design protocols for the development of the medical device in question).

Defendants argue that Plaintiffs have created a straw man regarding Dr. Pramudji by discussing certain Ethicon documents like design failure modes analysis, process, failure modes analysis, and failure modes effects analysis. (Defense Brief at 14, citing Plaintiffs' Memorandum at 9-12). But Plaintiffs were simply trying to ascertain what design standards Dr. Pramudji is relying on for her opinions. Nowhere do Defendants identify any standard or methodology applied by Dr. Pramudji, or by which Dr. Pramudji's opinions on the design of the product can be tested or objectively evaluated. As such, she should be precluded from giving any opinions related to the adequacy of the design of the mesh products.

C. Dr. Pramudji's should be precluded from giving any opinions regarding mesh degradation beyond testifying whether she has observed mesh degradation in her clinical practice.

Defendants misconstrue Plaintiffs' motion to preclude certain opinions of Dr. Pramudji with regard to mesh degradation. In the *Huskey* case, Defendants initially offered Dr. Pramudji as an expert on chemical degradation of polypropylene, but this opinion was withdrawn, reserving the right to call Dr. Pramudji to testify whether she has observed degradation in her clinical practice. (*See* Notice of Withdrawal of Certain Expert Ops. of Dr. Christina Pramudji and Dr. Wenzin Zheng [Docket 267] Case 2:12-cv-05201). Because the designation was withdrawn, this Court has never issued an opinion regarding Dr. Pramudji's qualifications to

testify on chemical degradation of polypropylene. Plaintiffs believe Dr. Pramudji should be precluded from testifying on that topic for the reasons stated in their initial memorandum and tacitly acknowledged by Defendants' withdraw of certain opinions in the *Huskey* case. This Court has previously ruled that Dr. Pramudji is qualified by her medical experience to testify whether or not she has observed mesh degradation in her clinical practice. *Huskey v. Ethicon*, 29 F. Supp. 3d 691, 726-27 (S.D West Virginia 2014). Plaintiffs are not seeking reconsideration, only to prevent Dr. Pramudji from expanding this opinion into other areas where she lacks qualifications such as chemical degradation of polypropylene. As such, Dr. Pramudji should be precluded from opining about mesh degradation, beyond testifying whether she has observed mesh degradation in her clinical practice**.**

CONCLUSION

For the foregoing reasons, Dr. Pramudji's opinions should be limited at trial.

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Respectfully submitted,

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CERTIFICATE OF SERCE

I hereby certify that I filed the foregoing document on May 16, 2016, using the Court's CM-ECF filing system, thereby sending notice of the filing to all counsel of record in this matter.

/s/ Thomas P. Cartmell
Attorney for Plaintiffs